Office Action Summary	Application No. 09/249,700	Applicant(s) EDGREN ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1615	

-- The MAILING DATE of this communication app ars on the cov r sheet with the correspondenc addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 1-27 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

ACTION SUMMARY

Claims 1-27 are rejected. Examiner acknowledges receipt of the Information Disclosure Statement filed 2/12/99.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim13 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: "is coated".

The omission of "is coated " in claim 13 makes the claim indefinite and inserting "is coated" between "composition" and "with" will complete the sentence in claim 13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. in view of Merrill et al.

Mayer et al. teaches that it is known to use opioid and nonopioid drug combinations for the alleviation of pain or treating other conditions associated with pain. (See column 1, lines 24-60). Specifically, Mayer et al. discloses a therapeutic composition comprising of pharmaceutically effective amount of a first and second analgesic in tablet, caplet or capsule dosage form. Specifically, Mayer et al. teaches that the first analgesic is an opioid and the second analgesic is a nonopioid. Examples of opioid analgesics taught by Mayer et al. are morphine, heroin, hydromorphone, oxymorphone, oxycodone, fentanyl and codeine and their pharmaceutically accepted salts. (See column 3, lines 57-65, and claim 1). Examples of nonopioid analgesics taught by Mayer et al. are acetaminophen, aspirin, ibuprofen, zomepirac, their mixtures and their pharmaceutically accepted salts. (See column 3, lines 65-67, and column 4, lines 1-7). Mayer et al. also teaches the therapeutic composition includes polyvinylpyrrolidone and condensation products of alkylene oxide as excipients. (See column 5, lines 14-23). However, Mayer et al. fails to disclose the presence of ethylcellulose, hydroxypropylcellulose and cellulose acetate. Mayer et al. is silent on the mg. amount of the dosage. Merrill et al. teaches hydromorphone therapy comprising of hydromorphone and its pharmaceutically accepted salts, polyvinylpyrrolidone, polyethylene oxide polymeric carrier, (column 2, lines 26-65), semipermeable wall of cellulose acetate (column 4, lines 36-40), and

selectively permeable wall of hydroxypropylcellulose and ethylcellulose (column 5, lines 39-56). Merrill et al. also teaches administering 1-1,000 mg. hydromorphone or pharmaceutically accepted salt to a patient.

The expected result is to deliver an extended, controlled and sustained dose of analgesic to a patient. The first and second analgesic formulation will be expected to replace a single analgesic formulation. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to design the drug combination of Mayer et al. in the manner taught by Merrill. One having ordinary skill in the art would have been motivated to do this in order to make available a drug combination of opioid and nonopioid analgesics that delivers an extended, controlled and linear dose in a variety of dosage forms.

Claims 15-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edgren et al. in view of Jao et al. and further in view of Merrill et al.

Edgren et al. discloses a dosage form comprising a first and second lamina for the controlled and prolonged delivery of a beneficial drug to a biological environment. (See column 2, lines 24-29) Each lamina comprises of polyvinylpyrrolidone, hydroxypropylcellulose, hydrooxypropylmethylcellulose, ferric oxide, and magnesium stearate. (See column 4, lines 30-41, and column 8, lines 45-61). Edgren et al. fails to teach an expandable layer. Jao et al. discloses a dosage form comprising continuous-release, extended release and prolonged-release forms (column 5, lines 18-22). Jao et al. further teaches a dosage form with an expandable layer comprising of polyethylene oxide (column 8, lines 6-41), and a wall comprising of cellulose acylate and cellulose acetate polymers (column 6, lines 9-40). Specifically, Jao et al. teaches an

exit port through which the dosage form communicates with the exterior. Jao et al. teaches an osmotic dosage form comprising of 0.5-90 weight % of an antiepileptic drug, and a pharmaceutically acceptable carrier comprising 10-75 weight % of a carboxymethylcellulose, and a 0.1-25 weight % of polyvinylpyrrolidone but does not teach the presence of opioid or nonopioid analgesic. However, Merrill et al. discloses hydromorphone dosage form comprising of hydromorphone and hydromorphone derivatives (column 5, lines 62-67 and column 6, lines 1-23), and polyethylene oxide and polyvinylpyrrolidone (claims 1-46).

The expected result is a continuous, sustained and prolonged rate-controlled delivery for administration of pharmaceutically beneficial agent from an osmotic dosage form. This type of dosing eliminates peaks, valleys and multiple administration of medicaments for the management of pain and other medical conditions. It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to design a laminated dosage form of Edgren et al. in the manner taught by Jao et al. to include the medicament of Merrill et al. One having ordinary skill in the art would have been motivated do this in order to design and manufacture a morphine (opioid) dosage form for the benefit of providing sustained level of drug in the hosts' system thereby eliminating peaks, valleys and multiple administration. One having ordinary skill in the art would have been motivated to make available a dosage form that will be better accepted by consumers in light of the benefits cited above.

The prior arts made of record and relied upon are considered pertinent to applicants' disclosure. Cortese et al. discloses an osmotic drug delivery device that simultaneously delivers two drugs. Sackler et al teaches an orally administered pharmaceutical dosage form of an opioid

analgesic (morphine) for once-a-day administration. Hamel et al teaches a laminated osmotic dosage form for co-administration of pseudoephedrine and brompheniramine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on Monday-Friday from 7 a.m. to 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.